vey was conducted in 87 cervical cancer patients admitted to Dr. Sardjito Hospital, a referral hospital in Yogyakarta Province-Indonesia, between June to December 2013. Data on HRQOL was collected using EQ-5D-3L (Indonesian version). As no Indonesian-EQ-5D-3L value set exists, Malaysian value set was used to calculate utility among these patients. **RESULTS:** About 14%, 51%, 31% and 5% of patients were in stage I to IV, respectively. The most frequently reported problems were pain/discomfort (67.82%) and anxiety/depression (57.47%). The mean of EQ-5D VAS score was 75.83 (SD=17.03). The mean utility value was 0.830 (SD=0.182), 0.751 (SD=0.188), 0.704 (SD=0.205), and 0.766 (SD=0.131) for patients with stage I to IV, respectively. Based on the stage of cervical cancer, the proportion of patients reporting problems in each dimension tended to increase from stage I to stage IV while the EQ-5D VAS score tended to decrease from stage I to stage IV. The utility value also tended to decrease from stage I to stage III, however it rather increased for patients with stage IV. **CONCLUSIONS:** Cervical cancer significantly affects patient's HRQOL. Effort should be made to improve the quality of life of cervical cancer patients especially in term of pain /discomfort and anxiety/depression reduction.

CANCER – Health Care Use & Policy Studies

PCN37
INSURANCE COVERAGE POLICIES FOR COMPANION DIAGNOSTICS IN BREAST CANCER

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OBJECTIVES: Personalized medicine along with successful delivery of novel diagnostics has potential to revolutionize the patient care. However, the major challenge includes reimbursement system, specifically in obtaining coverage, appropriate coding, and value-based payment for diagnostics. To determine the coverage policies, extent of the tests covered and evidence basis for the coverage decisions by U.S. payers for genomic tests in breast cancer. **METHODS:** We reviewed the coverage policies for genomic tests in breast cancer, coverage extent, and evidence for coverage decisions. An online search of top US insurers was conducted in January 2014 to identify the coverage policies for genomic tests. In addition to FDA approval, the coverage policy and assessments were also reviewed. **RESULTS:** In this search of insurance companies, 22 coverage policies for genomic testing were identified. Coverage determinations were made for 5 unique tests for disease diagnosis, prognosis and risk assessment in the 22 policies analyzed. For genomic tests in Breast Cancer, one of the 5 tests was approved by the FDA and covered by only one insurer that issued a coverage decision on it. Coverage policies specific to disease-related genomic tests varied across the insurance companies that were evaluated. The Oncotype Dx is covered by all insurers to assess breast cancer recurrence risk, but considered investigational. Only 2 diagnostic tests were covered by atleast one insurer, however one of the tests was reviewed and covered by all insurers. Humana covered two tests; Mammaprint and Oncotype DX. The Mammaprint test for breast cancer risk recurrence had discordant coverage policies among tests reviewed by more than one insurer. **CONCLUSIONS:** Although some insurers are willing to provide coverage based on limited evidence of clinical utility, insurance coverage for genomic testing is low and variable. This is likely due to few studies published that demonstrate clinical utility and availability of alternative screening methods.

PCN38
ECONOMIC IMPACT OF GENETIC DIAGNOSTIC TEST FOR BREAST CANCER - HEALTH TECHNOLOGY ASSESSMENT IN SLOVAK HEALTH CARE ENVIRONMENT

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OBJECTIVES: To explore the effects of genetic testing of patients with breast cancer by Oncotype DX for decision of further therapy and their prognosis. **METHODS:** Health economy model, using Cost-Utility Analysis (CUA), complemented by Budget-Impact Analysis (BIA) on public health insurance coverage in Slovakia. Markov Model (life time horizon) for BC patient management was developed, comparing diagnosis by Oncotype DX and standard diagnostic methods. Outcomes observed were decreased by number of women with chemotherapy (CT) and increased by proportion of women with hormonal treatment alone (HT) and their Recurence Score (RS, observed from test) in horizon of 10 years. Payer perspective and direct health care costs only, associated with breast cancer diagnoses patient management were considered in CUA and BIA for diagnosis subgroups. Discount rate of 5% was used for costs as well as outcomes. Sensitivity analysis for major complications was implemented. **RESULTS:** CUA for Oncotype DX vs. standard care associated with decreased proportion of CT and increased proportion of HT with cost per QALY 12 889 € and cost per LY 11 019 €. Net costs (BIA) associated with Oncotype DX for cohort of patients 1 200 are 3.92 mil. €. **CONCLUSIONS:** Oncotype DX is considered cost-effective in terms of diagnoses and followed treatment of breast cancer patients. Oncologists are able to differentiate between a low or intermediate RS and a high RS using standard prognostic criteria. Provision of the actual RS changed the treatment recommendations in nearly 40% of cases, suggesting that the RS may reduce chemotherapy use.

PCN39
THE DIFFERENCES BETWEEN CANCER DRUG APPROVALS IN JAPAN AND THE USA

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OBJECTIVES: Cancer is amongst the leading causes of death globally and was responsible for a total of 8.2 million deaths worldwide in 2012. The aim of this study was to investigate the similarities and differences between the approval of new molecular entities and biologics for the treatment of cancers in Japan and the USA. **METHODS:** Drugs approved from 2004 to 2013 were identified through publically available reports on the USA Food and Drug Administration (FDA) and the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) websites. Relevant drugs were defined as related to the treatment of neoplasms, according to the World Health Organisation International Classification of Diseases Version 2010. **RESULTS:** The FDA approved a total of 55 cancer drugs between 2004 and 2013 compared to 45 by the PMDA, of which 24 drugs were approved by both organisations. Although less than half of currently FDA-approved cancer drugs are approved by the PMDA, 87.5% of drugs approved by the FDA between 2004 and 2007 have subsequently been approved by the PMDA with an average delay of 2.95 years. Of the total number of drugs for all indications, 21% of FDA-approved drugs and 16% of PMDA-approved drugs were indicated for oncology. Although the proportion of drugs focused on breast cancer, lymphoma and bone marrow disorders were similar between the two organisations; the FDA had a higher proportion of drugs indicated for leukemias and prostate cancer, whilst the PMDA had a larger focus on colorectal cancer drugs. **CONCLUSIONS:** From the analysis presented here, there are clear differences between cancer drug approval in Japan and the USA with regards to time-to-approval of new drugs, as well as the specific treatment areas for which new drugs have been submitted.

PCN40
CHANGE IN PERCENTAGE OF LEFT VENTRICULAR EJECTION FRACTION IN BREAST CANCER PATIENTS RECEIVED TRASTUZUMAB TREATMENT

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OBJECTIVES: To review prevalence and risk factors of trastuzumab's cardiotoxic effects in breast cancer patients. **METHODS:** Retrospective chart review of 20 cases recieved trastuzumab for breast cancer treatment at Phramongkutklao hospital during 2010-2011. **RESULTS:** Average age of patients in this study was 58.2 +/- 9.3 years old. The most common stage of breast cancer were stage III (11/20, 55%). Average cycle per patients was 21.3 +/- 10.1. There were 12 patients (60%) completed 1 year course of treatment, 7 patients still recieving the treatment and 1 patient had to discontinue treatment before completion. There were 13 patients (65%) had declining in percentage of left ventricular ejection fraction after trastuzumab treatment, 6 (46%) patients had less than 10% declining of left ventricular ejection fraction, equal to number of patients with 11-20% declining of left ventricular ejection fraction (6 out of 12, 50%). In this study, we found 1 patients who had to discontinue treatment due to over 20% declining of ejection fraction. Due to the small number of cases, we did not found any statistical significant for the risk factors associated with the declining in ejection fraction among patients recieved trastuzumab treatment in this study. **CONCLUSIONS:** Cardiotoxicy in term of declining in percentage of left ventricular ejection fraction was not uncommon among breast cancer treated with trastuzumab. Closely monitoring patients with schedule echocardiogram is warranted for safety use of this drug.

PCN41
CANCER TREATMENT IN CHINA: HOW ARE POLICY AND PRACTICE IN TIER 1 VERSUS TIER 2/3 CITIES IMPACTING PATIENT ACCESS TO HIGH-COST THERAPIES

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OBJECTIVES: The Chinese oncology market is increasingly important to multinational and local pharmaceutical companies. However, access to high-cost medicines is fragmented within China. This study explored current prescribing and reimbursement of high-cost, targeted therapies and differences between Tier 1 and Tier 2/3 cities. **METHODS:** Some 76 oncologists from different tier cities were surveyed regarding their current and expected future prescribing for gastric cancer (GC) and hepatocellular carcinoma (HCC). In addition, payers who influence reimbursement at national and/or regional levels were interviewed. **RESULTS:** Chemotherapy still dominates GC and HCC treatment in China, with limited use of high-cost targeted therapies; reimbursement is considered the greatest barrier to accessing targeted therapies. Almost 60% of HCC patients do not receive sorafenib due to cost/reimbursement-related reasons. Patient assistance programs and private insurance schemes, along with government initiatives such as negotiation for selective provincial formularies inclusion and "disastrous diseases" coverage will help break this barrier. Patient share of high-cost GC and HCC therapies is expected to double over the next three years. We also found disparity in access to cancer therapies between different tier cities. More patients in Tier 1 cities have urban resident basic medical insurance than in Tier 2/3 cities (34% versus 24%). In Tier 1 cities, relatively more patients receive targeted therapy (23% versus 16%), compared with Tier 2/3 cities. Another compounding factor is that the cost of these therapies is lower in Tier 1 cities than in most Tier 2/3 cities (trastuzumab costs $1800 per cycle in Shanghai versus $2500 in Shijiazhuang). **CONCLUSIONS:** There is huge opportunity for high-cost cancer therapies in China; however, uneven reimbursement between cities means local market access strategies are required to maximize patient share.

PCN42
IN VITRO DRUG RELEASE AND EX VIVO PERMEATION STUDY OF PREPARED MOUTH DISSOLVING TABLETS OF FLUCONAZOLE THROUGH PORCINE BUCCAL MUCOSA

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OBJECTIVES: Aim of the study was concerned with formulation and evaluation of mouth dissolving tablets. Fluconazole is a broad spectrum triazole derivative useful in treatment of oropharyngeal and esophageal candidiasis, but it is poorly water soluble drug, for that an attempt was made to form complex with β-Cyclodextrin to make it water soluble and then deliver via buccal mucosa. **METHODS:** The tablets were prepared by wet granulation method using permeation enhancer and solubilizing agent β-Cyclodextrin and other excipients using 3^2 factorial designs. The amount of drug in each tablet was 50 mg and average weight of each tablet was found to be 230 mg. The prepared tablets were evaluated and compared *in*